Office Action Summary	Application No.	Applicant(s)	
	10/587,819	CHAUHAN, ANIL K.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,11-13,15 and 18-23* is/are pending in the application.

4a) Of the above claim(s) *1,3-5,9,11-13,15,19,20 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 6, 18, 21, 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *08/12/2008; 4/21/2009*.
4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. *2/7/2011* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment, filed 12/01/2010, has been entered.

Claims 7, 8, 10, 14, 16, 17 have been canceled.

Claims 1-6, 9, 11-13, 15 and 18-23 are pending.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to elect a specific disease as recited in claims 21 and 23.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: claim 2, for example.

Election/Restrictions

Applicant's election without traverse of Group II in the reply filed on 12/01/2010 and oral election of species systemic lupus erythematosus (SLE) made during a telephonic conversation with Examiner on 2/7/2011 is acknowledged. Affirmation of the oral species election must be made by applicant in replying to this Office action.

Claims 1, 3-5, 9, 11-13, 15, 19-20, 22 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 2, 6, 18, 21, 23 are currently under examination as they read on a method for inhibiting the non-covalent association of membrane attach complex comprising administering an inhibitor that is a monoclonal antibody to a patient suffering from SLE.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 08/12/2008 and 04/21/2009 have been considered by the examiner.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Applicant is requested to identify the written support for the original claim 2 particularly the claimed limitations of "**a monoclonal antibody**". Applicant is invited to amend the specification to provide antecedent basis for the claimed subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6, 18, 21, 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Given a lack of antigen specificity disclosed regarding the recited monoclonal antibody, the following grounds of rejection are set forth.

There is insufficient written description of the genus encompassed by the recitation of "**monoclonal antibody**" because it does not recite any antigen specificity

thus reads on *any* monoclonal antibody.

The claims require the monoclonal antibody to have the functional property of inhibiting non-covalent association of membrane attack complex (MAC) and circulating immune complex (CIC). However, the claim does not define any antigen specificity and the specification as-filed is silent on any monoclonal antibody.

Antibodies are glycoproteins that possess the ability to react in vitro and in vivo specifically and selectively with the antigenic determinants or epitopes eliciting their production or with an antigenic determinant closely related to the homologous antigen.

Antibodies are immunoglobulins that are formed in response to immunogens or that are screened for specificity an antigen / immunogen.

It has been well established in the art that the antigen binding specificity is critical to how the skilled artisan would employ antibodies in various modalities (e.g., affinity purification, detection or diagnostic assays, bioassays, treatment), including those consistent with the instant.

However, the instant claims do not recite an antigen specificity for and the specification does not describe an actual reduction to practice or a partial structures, or physical properties, or chemical properties of any other monoclonal antibody that would have the function of inhibiting the association of MAC an CIC. For example, there is no information regarding what structural features would likely be associated with such inhibition activity of the monoclonal antibody. Thus, the specification does not disclose a correlation between selective inhibitory activity and the critical structure of a putative monoclonal antibody beyond the.

Given the well known polymorphism of antibodies, the level of the skill and knowledge in the art is that, beyond the disclosed function of the monoclonal antibody, there are no known correlation between any structural component and the ability to selectively inhibit association of MAC and CIC for the genus of monoclonal antibody encompassed by the claim. Thus, the disclosure does not allow one of skill in the art to visualize or recognize the structure or the antigen specificity of any monoclonal antibody required to practice the claimed invention.

Accordingly, one of skill in the art would conclude that Applicant would not have

been in possession of the claimed genus of "monoclonal antibody" because the structure of the genus of monoclonal antibody possessing the desired function and activity are not adequately described in the instant disclosure as-filed.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add New Matter.

Claim 2, 6, 18, 21, 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **enablement** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Given a lack of antigen specificity disclosed regarding the recited monoclonal antibody, the following grounds of rejection are set forth.

Antibodies are glycoproteins that possess the ability to react in vitro and in vivo specifically and selectively with the antigenic determinants or epitopes eliciting their production or with an antigenic determinant closely related to the homologous antigen.

Antibodies are immunoglobulins that are formed in response to immunogens or that are screened for specificity an antigen / immunogen.

It has been well established in the art that the antigen binding specificity is critical to how the skilled artisan would employ antibodies in various modalities (e.g., affinity purification, detection or diagnostic assays, bioassays, treatment), including those consistent with the instant disclosure.

However, the instant claims do not recite an antigen specificity.

The specification provides insufficient direction or guidance regarding how to make and use antibodies comprising the claimed function, i.e., inhibiting MAC and CIC association *in the absence of an antigen specificity*.

Given the well known polymorphism of antibodies, it would have been undue experimentation to make and use the vast repertoire of antibodies encompassed by the claimed invention in the absence of binding specificity to enable the scope of the claimed antibodies encompassed by the claimed invention.

Without sufficient guidance and given the well known complexity and unpredictability of using antibodies with no particular antigen specificity as well the well known polymorphism of antibodies; it would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue to make and use the vast repertoire of antibodies broadly encompassed by the claimed invention in order to make and use the antibodies consistent with the instant disclosure.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add New Matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 6, 18, 21, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al. (US Patent 6,355,245).

Evans et al. taught administering an anti-C5 monoclonal antibody to treat immune complex mediated disease such as SLE (see, e.g., column 1, lines 20-25 and column 2, line 33). Evans also taught that the anti-C5 monoclonal antibody has the activity of blocking the generation of activity of C5a and/or C5b active fragments of C5 thus inhibit the generation of C5b-9 MAC (see column 8, lines 55-65). By blocking MAC formation, one of ordinary skill in the art would readily appreciate that the prior art antibody would inhibits the association of MAC and CIC and complement fixation on CIC.

With respect to the limitation in claim 18, i.e., "*identifying an individual in need of reducing the symptoms cause by in creased complement fixation on circulating immune complex*", it is noted that the "*identifying*" step does not recite any physical method steps but simply states a characterization of those in need of treatment; such

"*identifying*" step may be performed entirely in the human mind and is not tied to any machine and does not transform any article into a different state or thing. Therefore, by virtue of treating those with SLE as taught by the prior art, Evans et al. meet the "identifying" limitation of the claim.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Primary Examiner, Art Unit 1644
February 24, 2011